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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/204,236 12/03/98 HAMILTON

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EXAMINER

NATH & ASSOCIATES
1030 FIFTEENTH STREET N W
SIXTH FLOOR
WASHINGTON DC 20005

CHANG, C

| ART UNIT | PAPER NUMBER |
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1612

DATE MAILED:

01/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|--------------------------------------|---------------------------------|
| Application No. 09/204,236 | Applicant(s) Hamilton |
| Examiner Celia Chang | Group Art Unit 1612 |

 Responsive to communication(s) filed on Oct 21, 1999. This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims Claim(s) 1-71 is/are pending in the application.

Of the above, claim(s) 12, 13, and 26-71 is/are withdrawn from consideration.

 Claim(s) _____ is/are allowed. Claim(s) 1-11 and 14-25 is/are rejected. Claim(s) _____ is/are objected to. Claims _____ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on _____ is/are objected to by the Examiner. The proposed drawing correction, filed on _____ is approved disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). 5,6,7,9,1C Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's election of group I in Paper No. 11, dated 10/21/99 is acknowledged.

Applicant's election with traverse of Group I in Paper No. 11, dated Oct. 21, 1999 is acknowledged. The traversal is on the ground(s) that there is no extra burden to search all the claims. This is not found persuasive because the reason for restriction is that the claims are drawn to independent and patentably distinct compounds which differ in elements, bonding arrangements and chemical properties to such an extend that a reference anticipates a compound would not render another compound in the same obvious.

According to MPEP 803.02 restriction for Markush claims, broadly, unity of invention exists where compounds included within a Markush group (I)share a common utility and (ii)share a substantial structural feature disclosed as being essential to that utility. From the above evidenced provided by applicants proviso out from the claims, no common core essential to the claimed utility can be found for the Markush claims.

It is noted that the compounds being proviso out at the end of claim 1 and the structural delineation submitted with the PTO-1449 have structural diversified rings for independent and distinct uses, e.g.:

CA 95:88473, n=1, D is bond, R2 is CON-OH, as antiinflammatory agent;

CA 130:24972 , n=2, D is bond, R2 is CON-OH, as metalloproteinase inhibitor.

It is further evidenced that not only the different size rings are structural material for distinct utility, but also the 2-substituents i.e. the different species being drawn to the different structure are patentably distinct and independent. In the event that applicant's traversal is also on the ground that the species are not patentably distinct, applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If such identification or admission were made, then there could have been no patentability of all the inventions over Aketa et al. CA 85:108,839 since RN 60369-21-3 anticipates the claims (please note that these are examples of the patentably distinct variations for R2 by sample search).

The requirement is still deemed proper and is therefore made FINAL.

Based on the election, the subject matter being examined are those compounds of claims 1-11 wherein n=1, R2 is CN or a bioisostere thereof.

Applicants did not elect a specific disease/pathology to be prosecuted with the elected species (incomplete response). Claims 14-25 are included in the examination to the scope of claim 16 and to the extend of the elected compounds. Claims 12-13 and 26-71 are withdrawn from consideration per 37 CFR 1.142(b).

An enormous number of prior art references have been submitted without description of relevancy. These references as cited on the 1449 have been given a **cursory** review commensurate to the manner they ar submitted.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Busson et al. CA 89:215152.

See RN 67488-67-9 delineated.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 55-153763 (cited on 1449).

See p.3, right column, compound # 36.

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3 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 89:215152.

The difference between the elected species and the Busson et al. is that the reference has a D is methylene chain while the elected compound has a different chain length. Variation in chain length is normally a skill within the chemical art for compound preparation in absence of unexpected results. In re Lohr 137 USPQ 548; in re Hoke 195 USPQ 148.

Claims 1-11, 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 55-215152; CA 118:80750 (1449) or WO 92/21313 in view of Anderson et al. CA 125:104525.

The JP 55-215152; CA 118:80750 (1449) or WO 92/21313 references disclosed the isostere ester with or without a linker between the ester moiety and the pyrrolidinyl ring. The difference between the claims and the references is that instead of ester, the elected species is drawn to R2 is cyano. The nitrile moiety is conventional isostere for the ester or amide carboxylic isostere as taught by Anderson.

One having ordinary skill in the art is well informed of the interchangeability between the various carboxylic isosteres and would be motivated to replace one with another with the expectation that such isosteres would have similar functionality.

4. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is unclear what is included in the claims because the definition of claims 1-4 included all possible compounds not yet been made i.e. carbocycle or heterocycle containing any combination of CH₂, O,S or N in any chemical stable oxidation state, and such cycle can be optionally substituted in any position with R3. The meets and bounds of the claims can not be delineated. At the same time, the claims listed confusing provisos of many compounds. Applicants are urged to clearly claim what is the particular invention not what is not.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Please note that on one hand the scope of the claims are unclear yet at the same time many known compounds are excluded from the claims. For those compounds has yet to be made, the how to make and use rejection is applicable. For those compounds wherein the carboxylic acid isostere are those delineated in claims 3 and 4, no evidence has been provided that those "chemical isostere" all have "bioisostere" properties, since not all chemical isostere are biological isostere functionally (see Thornber).

5. Claims 1-11, 14-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over patented claims of U.S. Patent No. 5,721,256 or 5,874,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because broadly the instant claims embraced the patented claims in addition, the proviso limiting D is a chain is an *prima facie* obvious modification of known compounds since chain homologs are expected to have similar activity as the known compound. *In re Lohr* 137 USPQ 548; *In re Hoke* 195 USPQ 148; *In re Fauque* 1211 USPQ 425.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-11, 14-25 are provisionally rejected under 35 U.S.C. 103(a) as being unpatentable over the corresponding US pending application of WO 99/10340.

Applicants attention is drawn to that the US pending application corresponding to the WO 99/10340 patent generically claims the instant compounds for the same use. The proviso limitation disclaimed certain species but does not obviated the generic scope as encompassed by the 99/10340 patent.

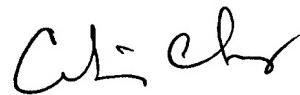
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is (703) 308-4702.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

CCC/Chang

Jan. 19, 2000


CEILA CHANG
PRIMARY EXAMINER
GROUP 1200 1612